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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

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RIN 0910–AB88

[Docket No. 96N–0417]

Dietary Supplements; Current Good Manufacturing Practice Proposed Regulation; Notice of Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; satellite downlink public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting (via satellite downlink) to discuss the proposed rule on current good manufacturing practice in manufacturing, packing, or holding dietary ingredients and dietary supplements that published in the **Federal Register** of March 13, 2003. This satellite downlink public meeting is intended to provide clarification of the proposed rule and to explain how to submit comments on the proposed rule. This meeting will provide stakeholders, including small business, an opportunity to ask questions about the proposed rule by telephone, e-mail, or FAX. Questions also may be submitted in advance of the satellite downlink public meeting until the day before the downlink (see **FOR FURTHER INFORMATION CONTACT** section of this document).

DATES: The public meeting via satellite downlink will be held on May 9, 2003, from 12:30 p.m. to 3:30 p.m. eastern daylight time.

ADDRESSES: Downlink sites for the public meeting will be Food and Drug Administration District and Regional Offices for FDA employees. Small

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businesses wishing to view the satellite downlink should contact their Regional Small Business Representative. Regional representatives are listed at the Office of Regulatory Affairs' Web site at: http://www.fda.gov/ora/fed_state/Small_business/sb_guide/smbusrep.htm, or go to http://www.fda.gov/ora/fed_state/events/default.htm for a list of public viewing sites.

State and local counterparts who wish to participate may consider any local viewing location that has access to a C-band steerable dish.

Viewers with access to a steerable dish capable of receiving a C-band satellite signal may wish to tune this meeting in themselves. Tuning coordinates and course materials will be placed on the Center for Food Safety and Applied Nutrition (CFSAN) Web site at: http://www.cfsan.fda.gov/~dms/supplmnt.html when available.

FOR FURTHER INFORMATION CONTACT: Bradford W. Williams, Center for Food Safety and Applied Nutrition (HFS–810), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, telephone: 301–436–1440, FAX: 301–436–2636, e-mail: Brad.Williams@cfsan.fda.gov for general questions about the downlink and submission of advance questions.

SUPPLEMENTARY INFORMATION:

I. Background

The Dietary Supplement Health and Education Act of 1994 (DSHEA) (Public Law 103–417) amended the Federal Food, Drug, and Cosmetic Act to, among other things, provide FDA with express statutory authority to prescribe current good manufacturing practice (CGMP) regulations for dietary supplements (21 U.S.C. 342(g)). In the **Federal Register** of March 13, 2003 (68 FR 12157), FDA published a proposed rule entitled "Current Good

Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements" to establish CGMPs that include provisions on manufacturing, packaging, labeling, testing, quality control, releasing for distribution, and holding of dietary ingredients and dietary supplements. The proposed CGMPs are intended to help ensure that manufacturing, packing, and holding practices will not result in an adulterated or misbranded dietary supplement.

This downlink meeting will provide an opportunity to brief stakeholders on the proposed rule and allow them to ask questions about the proposed rule. It is also intended to fulfill part of the outreach requirements of the Small Business Regulatory Enforcement Fairness Act of 1996. The half-day meeting will focus on information for manufacturers, both large and small, with an emphasis on assistance to small firms. Small firms are encouraged to view and participate in this downlink meeting.

II. Agenda

The agenda will include an overview of the proposed rule with the following specific topics: (1) Personnel, (2) physical plant, (3) equipment and utensils, (4) production and process controls, (5) holding and distribution, (6) consumer complaints, and (7) recordkeeping. In addition to explaining the content of the proposed rule, we will instruct participants on the process for submitting comments. We also will discuss the types of comments and supporting information that would be most helpful to the agency in developing a final rule. Lastly, the meeting will describe how the Small Business Administration (SBA) can help small firms that might be affected by the proposed rule.

The primary intended audience is dietary ingredient and dietary supplement manufacturers, packagers, distributors, and holders, including small businesses, their representatives and consultants; Federal, State and local representatives; and FDA small business representatives and other interested FDA staff. Viewers are encouraged to watch the satellite program and participate in the question and answer periods. Any interested parties with access to a satellite dish may view the downlink directly. For specific technical details, including tuning coordinates, check the CFSAN Web site at: http://www.cfsan.fda.gov/~dms/supplmnt.html under "Recent Announcements" before the meeting.

Before the broadcast, we suggest that interested parties read the section in the March 13, 2003 (68 FR 12157), proposed rule entitled "Proposal Highlights and Request for Comments," as well as the background document, fact sheet and the guidance for small businesses that are located at the CFSAN Web site noted above. In addition, a promotional flyer and specific technical tuning instructions will be added to the CFSAN Web site in the near future.

Questions may be submitted in advance of the satellite downlink public meeting until the day before the meeting (see the **FOR FURTHER INFORMATION CONTACT** section of this document).

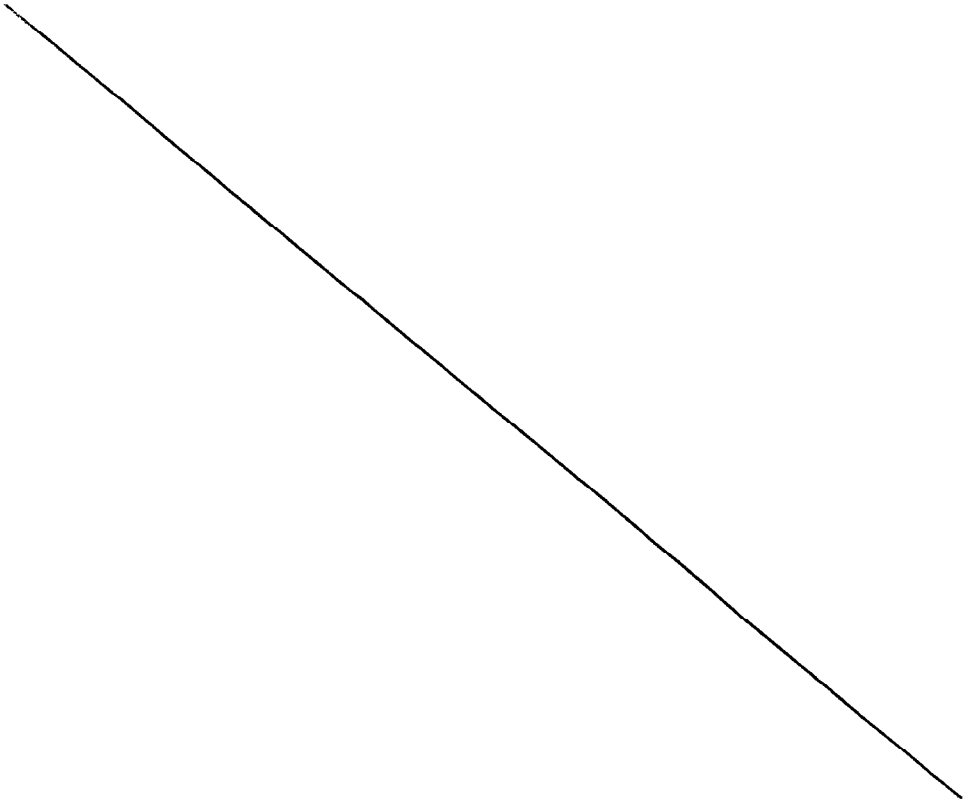
III. Transcripts

A transcript of the program and all questions/answers will be added to docket 96N–0417 and may be examined at the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday, as well as on the CFSAN Web site. You may request a transcript of the public meeting from the Freedom of Information Office (HFI–35), Food and Drug

Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 3 weeks after the meeting at a cost of 10 cents per page. In addition, a videotape of the satellite downlink public meeting will be available for viewing after the broadcast at the FDA Dockets Management Branch.

IV. Comments

To submit written comments on the proposed rule that published in the **Federal Register** of March 13, 2003, please follow the instructions in the



"Request for Comment" section of that document (68 FR 12157 at 12248), a copy of which may be found at CFSAN's Web site at: http://www.cfsan.fda.gov/~dms/supplmnt.html.

Dated: 4-15-03

April 15, 2003

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 03–????? Filed ??–??–03; 8:45 am]

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